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(c) If the awardee is convicted of a felony, or an offense involving any illegal drug or substance, or any offense involving a lack of financial integrity or business honesty; or

(d) Because of programmatic changes or lack of funds.

[65 FR 66513, Nov. 6, 2000]

§ 63.10 Other HHS regulations and policies that apply.

Several other policies and regulations apply to awards under this part. These include, but are not necessarily limited to:

45 CFR part 46—Protection of human subjects.

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants).

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of title VI of the Civil Rights Act of 1964.

45 CFR part 81—Practice and procedure for hearings under part 80 of this title.

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance.

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance.

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.

59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. (NOTE: Interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161; telephone 301-402-1770 (not a toll-free number) to obtain copies of this policy.)

59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules. (NOTE: Interested persons should contact the Office of Biotechnology Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010; telephone 301-496-9838 (not a toll-free number) to obtain copies of the policy.)

“Public Health Service Policy on Humane Care and Use of Laboratory Animals” (Revised September 1986), Office of Laboratory Animal Welfare, NIH. (NOTE: Interested persons should contact the Office of Laboratory Animal Welfare, NIH, Rockledge Building I, 6705 Rockledge Drive, Suite 1050, MSC 7982, Bethesda, MD 20892-7982;

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telephone 301-496-7163 (not a toll-free number) to obtain copies of the policy.)

[60 FR 10719, Feb. 27, 1995, as amended at 65 FR 66513, Nov. 6, 2000]

PART 63a—NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

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AUTHORITY: 42 U.S.C. 216, 242(b)(3), 284(b)(1)(C), 287c(b), 300cc-15(a)(1), 300cc-41(a)(3)(C), 7403(h)(2).

SOURCE: 61 FR 55111, Oct. 24, 1996, unless otherwise noted.

§ 63a.1 To what programs do these regulations apply?

(a) The regulations of this part apply to:

(1) Grants awarded by the John E. Fogarty International Center for Advanced Study in the Health Sciences, NIH, for training in international cooperative biomedical research endeavors, as authorized under section 307(b)(3) of the Act;

(2) Grants awarded by NIH for research training with respect to the human diseases, disorders, or other aspects of human health or biomedical research, for which the institute or other awarding component was established, for which fellowship support is not provided under section 487 of the Act and which is not residency training of physicians or other health professionals, as authorized by sections 405(b)(1)(C), 485B(b), 2315(a)(1), and 2354(a)(3)(C) of the Act; and,

(3) Grants awarded by the National Institute of Environmental Health Sciences, NIH, for the education and

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training of physicians in environmental health, as authorized under section 103(h)(2) of the Clean Air Act, as amended.

(b) The regulations of this part also apply to cooperative agreements awarded to support the training specified in paragraph (a) of this section. References to “grant(s)” shall include “cooperative agreement(s).”

(c) The regulations of this part do not apply to:

(1) Research training support under the National Research Service Awards Program (see part 66 of this chapter);

(2) Research training support under the NIH Center Grants programs (see part 52a of this chapter);

(3) Research training support under traineeship programs (see part 63 of this chapter);

(4) Research training support under the NIH AIDS Research Loan Repayment Program (see section 487A of the Act); or

(5) Research training support under the National Library of Medicine training grant programs (see part 64 of this chapter).

§ 63a.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

HHS means the Department of Health and Human Services.

NIH means the National Institutes of Health and its organizational components that award training grants.

Nonprofit as applied to any agency or institution, means an agency or institution which is a corporation or association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

Program director means the single individual named by the grantee in the grant application and approved by the Secretary, who is responsible for the management and conduct of the training program.

Project period See § 63a.8(a).

Secretary means the Secretary of Health and Human Services and any other official of HHS to whom the authority involved is delegated.

Stipend means a payment to an individual to help meet that individual's

subsistence expenses during the training period.

Training grant means an award of funds to an eligible agency or institution for a training program authorized under § 63a.1 to carry out one or more of the purposes set forth in § 63a.3.

§ 63a.3 What is the purpose of training grants?

The purpose of a training grant is to provide financial assistance to an eligible agency or institution to enable it to provide research training to individuals in the diagnosis, prevention, treatment, or control of human diseases or disorders, or other aspects of human health or biomedical research, or in environmental health, in order to increase the number of facilities which provide qualified training and the number of persons having special competence in these fields.

§ 63a.4 Who is eligible for a training grant?

(a) *General.* Except as otherwise provided in this section or as prohibited by law, any public or private for-profit or nonprofit agency, institution, or entity is eligible for a training grant.

(b) *International training grants for AIDS research.* Any international organization concerned with public health is eligible for a training grant to support individuals for research training relating to acquired immunodeficiency syndrome (AIDS), as authorized under section 2315(a)(1) of the Act. In awarding these grants, preference shall be given to:

(1) Training activities conducted by, or in cooperation with, the World Health Organization and

(2) With respect to training activities in the Western Hemisphere, activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

§ 63a.5 How to apply for a training grant.

Any agency, institution, or entity interested in applying for a grant under this part must submit an application at the time and in the form and manner that the Secretary may require.

§ 63a.6 How are training grant applications evaluated?

The Secretary shall evaluate applications through the officers and employees, experts, consultants, or groups engaged by the Secretary for that purpose, including review or consultation with the appropriate advisory council or other body as may be required by law. The Secretary's evaluation will be for merit and shall take into account, among other pertinent factors, the significance of the program, the qualifications and competency of the program director and proposed staff, the adequacy of the selection criteria for trainees under the program, the adequacy of the applicant's resources available for the program, and the amount of grant funds necessary for completion of its objectives.

§ 63a.7 Awards.

Criteria. Within the limits of available funds, the Secretary may award training grants for training programs which:

- (a) Are determined to be meritorious, and
- (b) Best carry out the purposes of the particular statutory program described in § 63a.1 and the regulations of this part.

§ 63a.8 How long does grant support last?

(a) The notice of the grant award specifies how long the Secretary intends to support the project without requiring the grantee to re compete for funds. This period, called the "project period," will usually be for one to five years.

(b) Generally, the grant will be initially for one year and subsequent continuation awards will be for one year at a time. A grantee must submit a separate application at the time and in the form and manner that the Secretary may require to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of these awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require determination by the Secretary that con-

tinued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) Any balance of federally obligated grant funds remaining unobligated by the grantee at the end of a budget period may be carried forward to the next budget period, for use as prescribed by the Secretary, provided that a continuation award is made. If at any time during a budget period it becomes apparent to the Secretary that the amount of Federal funds awarded and available to the grantee for that period, including any unobligated balance carried forward from prior periods, exceeds the grantee's needs for that period, the Secretary may adjust the amounts awarded by withdrawing the excess.

§ 63a.9 What are the terms and conditions of awards?

In addition to the requirements imposed by law, grants awarded under this part are subject to any terms and conditions imposed by the Secretary to carry out the purpose of the grant or assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

§ 63a.10 How may training grant funds be spent?

(a) *Authorized expenditures; general.* A grantee shall expend funds it receives under this part solely in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the grant award, and the applicable cost principles in 45 CFR 74.27.

(b) *Authorized categories of expenditures.* Subject to any limitations imposed in the approved application and budget or as a condition of the award, grant funds may be expended for the following costs:

- (1) Expenses of the grantee in providing training and instruction under

the particular program, including salaries of faculty and support personnel, and the costs of equipment and supplies;

(2) Stipends and allowances to individuals during the period of their training and instruction; and,

(3) If separately justified and authorized under the particular program, tuition, fees, and trainee travel expenses which are necessary to carry out the purpose of the training grant.

(c) *Expenditures not authorized.* Grant funds may not be expended for:

(1) Compensation for employment or for the performance of personal services by individuals receiving training and instruction; or

(2) Payments to any individual who does not meet the minimum qualifications for training and instruction established by the grantee and approved by the Secretary or who has failed to demonstrate satisfactory participation in the training in accordance with the usual standards and procedures of the grantee.

§ 63a.11 Other HHS regulations and policies that apply.

Several other HHS regulations and policies apply to this part. These include, but are not necessarily limited to:

42 CFR part 50, subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science

42 CFR part 50, subpart D—Public Health Service grant appeals procedure

45 CFR part 16—Procedures of the Departmental Grant Appeals Board

45 CFR part 46—Protection of human subjects

45 CFR part 74—Uniform administrative requirements for awards and subawards to institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations; and certain grants and agreements with states, local governments and Indian tribal governments

45 CFR part 75—Informal grant appeals procedures

45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants)

45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of title VI of the Civil Rights Act of 1964

45 CFR part 81—Practice and procedure for hearings under part 80 of this title

45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance

45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments

45 CFR part 93—New restrictions on lobbying
59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. [Note: this policy is subject to change, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161 (301-402-1770; not a toll-free number) to obtain references to the current version and any amendments.]

59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules. [Note: this policy is subject to change, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010 (301-496-9838; not a toll-free number) to obtain references to the current version and any amendments.]

“PHS Grants Policy Statement,” DHHS Publication No. (OASH) 94-50,000 (Revised April 1, 1994), as amended by the Addendum, dated January 24, 1995. [Note: this policy is subject to change, and interested persons should contact the Extramural Outreach and Information Resources Office (EOIRO), Office of Extramural Research, 6701 Rockledge Drive, Room 6208, MSC 7910, Bethesda, MD 20892-7910 (301-435-0714; not a toll-free number) to obtain references to the current version and any amendments. Information may also be obtained by contacting the EOIRO via its e-mail address (ask_nih@odrockml.od.nih.gov) and by browsing the NIH Home Page site on the World Wide Web (<http://www.nih.gov>).]

“Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Office for Protection from Research Risks, NIH (Revised September 1986).

[NOTE: This policy is subject to change, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20852-7507 (301-496-7005; not a toll-free number) to obtain references to the current version and any amendments.]